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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	5

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

mk. 4

Office Action Summary	Application No.	Applicant(s)	
	09/811,780	APPU RAO ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any* earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice, and contain several grammatical and idiomatic errors. Correction is required.

- Claim 1, line 1: the term "a" should be inserted between the terms "of" and "protein".
- Claim 1, line 2: the term "an" should be inserted between the terms "hydrolyzing" and "aqueous".
- Claim 1, line 3: the term "a" should be inserted between the terms "using" and "proteolytic".
- Claim 4: it appears that the term "w/w/" should be "w/w".
- Claim 5: "effect" should be "effected".
- Claim 6: the term "wherein" should be inserted after "claim 1,".
- Claim 11: ending the claim with the word "taken" is grammatically improper, and confusing.
- Claim 20: line 1, the term "lour" is confusing; it is suggested that this term be amended to the term "from".
- Claim 20: line 3, a comma " , " should be inserted to separate "salt content" and "3 to 5%".
- Claim 27: the phrase "has cream color" is indefinite, does not set forth what part, if not all, of the hydrolysate "has cream color." It is suggested that this be amended to "which is the color of cream", or "which is cream-colored."

Each instance of a range, for example in claim 1, "containing 6-30%", is suggested to be amended to recite "containing from 6-30%", as this indicates the percentage range is "from 6 to 30".

Particularly, the recitation of "stirring for 30 minutes to 6 hours", in claim 1, does not clearly set forth that this is a range; obviously, if one stirred "to 6 hours", one would eventually go from "30 minutes to 6 hours". It is suggested that the claim be amended to recite "stirring for a range of from 30 minutes to 6 hours".

The phrase "by a known matter", in claim 1, is indefinite, as this does not serve to set forth the metes and bounds of the claim, such that applicants have clearly defined the invention. It is unclear by what means the enzyme is inactivated, or the solids separated. Further, it is unclear to whom this method is "known". Finally, the phrase would be "by a known manner", i.e. by a known procedure, as in the second occurrence at line 6.

In claim 1, the phrase "neutralizing the pH value of the slurry" is indefinite, as (a) it is unclear if this means a pH absolute of 7, or if this indicates a certain "neutral range", and (b) it is unclear what one skilled in the art is to do if the pH is already at 7 (i.e. "neutral").

In claim 1, line 6, it is suggested that the term "resultant" be inserted before "clarified liquor". As it stands, this phrase lacks a clear antecedent basis within the claim.

In claim 1, it is suggested that the phrase "so obtained to get the said hydrolysate", be amended to more clearly distinguish what is "obtained", between the liquor and hydrolysate, and to not use the phrase "to get". It is suggested that the phrase be amended to recite "... drying the resultant clarified liquor to obtain said hydrolysate."

In claim 1, line 3, the term "using" is suggested to be amended to recite "with a", as in "hydrolyzing... with a proteolytic enzyme".

In claim 3, the phrase "selected from the group comprising of" is indefinite. The term "comprising" has been deemed and accepted as open claim language, which conflicts with the closed set language of "selected from the group consisting of", which the claim is suggested to recite.

In claim 6, line 2, the term "and" should be "or", to properly set forth the optional limitations. It is not believed that all three drying methods are to be utilized.

The terms recited immediately below, are relative terms which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

- "decreased" (claim 7)
- "less... in nature" (claim 8); additionally, the necessity of the phrase "in nature" is unclear.
- "low" (claim 10)
- "high" (claim 11)
- "creamy" (claim 12)
- "was similar to" (claims 16, 23): it is unclear as to what properties are utilized, and to what degree, such that one item "was similar to" another.
- "undesirable flavor" (claims 18 and 25): it is unclear who determines what is "undesirable", and what these flavors comprise.

The phrase "bitterness recognition threshold", in claims 9 and 22, is indefinite. It is unclear as to what type of measurement this provides, how it is performed, if this is a standard test in the art, and, as phrased in the claims, if this is an actual unit of measurement (i.e. "2 g/100 ml bitterness recognition threshold *units*"). Similarly, the phrase "has... Nitrogen Solubility Index", in claims 14 and 20, is unclear.

The use of parentheses, for example, in claim 12, renders the claims indefinite, as it is unclear if the limitations recited therein, are part of the actual claimed invention. Deletion of the parentheses is suggested.

In claims 17 and 24, the phrase "retained the nutrition value as in the starting material", is indefinite on several accounts. It is unclear as to what properties or elements are required for "nutrition value" to be retained. Further, the phrase "as in" does not clearly set forth a direct comparative relationship.

In claims 16 and 23, the phrase "amino acid makeup" (of the starting material) is unclear, with regard to its "similarity to" the "amino acid composition" (of the hydrolysate). If these are to indicate the same metes and bounds, to maintain continuity, it is suggested that the phrase "amino acid composition" be maintained throughout.

Claims 18 and 25 are indefinite, as it is unclear as to what constitutes "the finished product". It appears from independent claims 1 and 20, that the protein hydrolysate *is* the finished product, and thus the distinction between the two, such that one may impart flavors to the other, is unclear.

In claim 22, the phrase "further comprising" is suggested to be amended to delete the term "further." As it stands, it appears that some additional component not originally present in the hydrolysate composition of claim 20 (i.e. "*further* comprising"), lends the bitterness recognition threshold (units?).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrue.

Delrue discloses a process for making a soy protein hydrolysate, by preparing an aqueous slurry of defatted soy flour (col. 3, lines 55-56) containing "between about 15 to about 35 weight percent dry solids" (col. 4, line 31), preferably "about 21 percent dry solids by weight" (col. 3, line 18), and hydrolyzing the slurry by mixing it with a carbohydrase, and a protease from various sources, including papain from plant (col. 6, lines 44-49). "The pH of the slurry is adjusted between about 3.5 to about 6", at a temperature of from 30°C to 60°C" (col. 4), specifically between 42-51°C under continuous stirring (example 6), where the reaction time is "about 4 hours" (top col. 6; example 6). "The protease is employed to hydrolyze the proteins and to increase the solubility of the final proteinaceous product" (col. 6, lines 55-58). Subsequently, the treated slurry is heated, whereby "unwanted proteinaceous antinutritional factors are inactivated substantially" (col. 5, lines 54-56). "By using lower temperatures, the color of the final proteinaceous product is lighter" (end col. 5). The slurry may be decanted, such that "continuous solids are separated from suspensions" (top col. 8). After the hydrolyzation, the mixture is pasteurized at high temperatures, and optionally, "the slurry can be corrected with sodium hydroxide or sodium carbonate or calcium hydroxide to obtain a pH of about 5.0 to about 6.5. The proteinaceous matter is dried by flash drying or spray drying" (col. 8, lines 7-17). "The dried product is a free-flowing product and contains substantially no antinutritional factors and antigenicity factors... The level of trypsin inhibitor is lower than 1.0 (mg trypsin inhibited per gram of product)" (col. 8, ln 37-42).

The dried product has "about 3 to about 11 percent moisture" (col. 8, ln. 23). The amount of protease added is provided at column 7, lines 44-65, in varying activities and amounts, based upon either the dry product, or the slurry weight (which additionally contains water by weight). These would be expected to fall within the instantly-claimed range as recited in claim 4. Further, "the standard reaction time... can be varied according to the dry solids content of the slurry and the amount of enzymes used" (col. 6, ln. 8-11). The reference addressed the "proteinaceous antinutritional factors" being present in negligible amounts "substantially no" such components present. Thus, the trypsin inhibiting factors, lipoxygenase and urease activities would have been inactivated as a result of the heating process, as well.

As the reference meets the claim limitations with regard to the instant method steps, as well as the actual resultant product, the particular properties of the product recited in the instant claims would be considered inherent to that product, absent any clear and convincing evidence and/or arguments to the contrary, showing why one would not expect the same starting materials and the same method to result in the same product as that claimed. For example, the pasteurization step would denature, and thus inherently inactivate, the enzymatic activity at such high temperatures. The color of the final product

would be expected to be cream in color, based upon a starting soy material, and the fact that the reference stated that "the color of the final proteinaceous product is lighter" with low temperature treatment after hydrolyzation. The properties of being "less hygroscopic", the range of bitterness, mineral content (including nitrogen and salt) and flavor, would all be considered inherent to the disclosed product, as these were intrinsic to both the starting material as well as the result of the method steps performed and disclosed. While a degree of hydrolysis was not specifically provided, this, too, would have been an inherent property of the hydrolyzed soy product, based upon the same starting material, the same plant protease enzyme (papain), the same times, temperatures, pH and other conditions, all which would be expected to render a soy product with a degree of hydrolysis (DH) within the claimed range. The DH of a product would be dependent upon those factors, and thus it would follow that those factors would lead to the same product, or a very similar product which falls within the instantly-claimed ranges.

Thus, the reference anticipates the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER